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Declaration
D. Boyce
10/9/02

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Leo A. Whiteside
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EXAMINER: Bruce E. Snow
DOCKET NO.: WBC 7403US
GROUP ART UNIT: 3738
FOR: Acetabular Component With Improved Liner Seal and Lock

Commissioner of Patents
Washington, DC 20231

September 20, 2002
St. Louis, Missouri

DECLARATION OF LEO A. WHITESIDE SUBMITTED IN ACCORDANCE WITH 37 CFR §1.132

I, the below named Declarant, state and say the following:

1. My name is Leo A. Whiteside, and I reside at 14825 Sugarwood Trial, Chesterfield, Missouri 63017.

2. I am the inventor of the above-identified re-issue patent application.

3. I am an orthopedic surgeon and I have over 30 years' experience. I have performed hundreds of knee and hip replacement surgeries. I developed and tested numerous orthopedic devices, including components for total knee and hip replacement systems and instrumentation for performing such surgeries. I have over 25 patents on orthopedic appliances and instrumentation. I have served as an opinion leader and consultant on knee and hip replacement systems and instrumentation to several major

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orthopedic appliance manufacturers. I have taught numerous short courses from orthopedic surgeons all over the world relating to knee and hip replacement surgery.

4. I am the owner of the Whiteside Biomechanics, Inc., the assignee of the above-identified patent application. Whiteside Biomechanics, Inc. carries out research on, designs, develops, manufactures and markets a variety of products for the orthopedic industry, including knee and hip replacement systems.

5. The invention described and claimed in the above-identified patent application is a prosthesis device (as described in claim 10), or a component for an orthopedic joint replacement system (as described in claim 12). I have read and understand these claims.

6. These devices, as claimed, solve two major and long-standing problems theretofore experienced with prior similar devices. First, the seals in the devices of my invention effectively prevent "joint fluid" from coming into contact with resected bone surfaces which leads to bone loss and loosening of the appliances. Secondly, the polyethylene[1] liners of these devices are securely locked to the metal component thereby preventing micro-motion movements of the liner with respect its metal component which leads to excess wear of the liner and which generates polyethylene debris which has been found to be detrimental to the service life of the prosthesis device.

7. The comments that I make in this Declaration are directed to the orthopedic joint replacement system of claim 12, but my comments apply equally as well to the prosthesis device of claim 10.

[1] Note, when I refer to a "polyethylene" component or liner, I am referring to the component that in most conventional prosthesis devices are made of plastic, typically polyethylene. However, by so referring to a polyethylene component, it is through normal usage that I refer to this material and I do not mean to infer or limit in any way that this component must be made of polyethylene or any other particular material.

8. While the orthopedic joint replacement system of claim 12 may apply to any joint in the human body, it is particularly described in relation to an acetabular component for a hip replacement system.

9. In such orthopedic joint replacement prosthesis systems, there are typically two components that cooperate with one another to replace the joint. In a hip replacement system, the components include an acetabular component and a femoral component. As is widely known, the hip joint is typically characterized as a "ball and socket" joint. The acetabular component serves as the socket and the femoral component has a ball one its end that is received within the socket of the acetabular component.

10. As is commonly known, an acetabular component comprises a liner and a shell or housing. The liner is formed of a suitable plastic material, such as polyethylene, and shell is metal cup for holding the liner with the cup being affixed to the bone structure of the pelvis in place of the acetabulum.

11. In hip replacement systems, I have found that two of the most important features of such systems are: 1.) the provision of an effective seal between the interface of the polyethylene liner and the metal cup or shell, and 2.) a locking mechanism to insure that the polyethylene component is securely locked with respect to its shell so as to effectively prevent micro-motion movement of the liner with respect to the shell or housing as the patients walks or does other repetitive activities that subject the joint to movement or repeated weight bearing.

12. It should also be borne in mind that during the surgery, the metal component is typically installed on the bone and then the polyethylene component is inserted into the metal component by the surgeon. Thus, not only is it necessary that the

polyethylene component both be sealed and securely locked with respect to the metal component, but the installation of the polyethylene component must not require undue forces or time for the surgeon to install it in the metal component. The installation must be easy to do, it must effectively seal, and it must firmly lock the polyethylene component to the metal component. This seal and locking arrangement must hold up for millions of stress and weight bearing cycles.

13. A common problem encountered with joint replacement systems is the development of osteolysis (i.e., bone dissolution and destruction caused by joint fluid and particulate debris being pressurized into the bone and by movement between the prosthesis device and the supporting bone structure to which the device is secured).

14. Intra-articular hydraulic pressure occurs routinely after total joint replacement because of the accumulation of fluid "effusion" in the joint. This relatively high pressure can drive the synovial fluid (i.e., a transparent viscid lubricating fluid secreted by a membrane of an articulation or tendon sheath, also commonly referred to as "joint fluid") into the bone proximate the joint causing cyst formation that undermines the implant component leading to loosening of the component, which, in turn, and can lead to catastrophic loss of the supporting bone structure.

15. This process of bone de-generation is worsened by such things as screw holes or channels in the metal shell of the prosthesis device that allow the joint fluid, especially when acting under pressure, to enter the supporting bone stock behind the metal shell of the device where the metal shell is affixed to the bone stock either by cement or by fasteners.

16. When first introduced, most of the hip replacement systems used cemented, all polyethylene cups that were fixed to the resected, porous bone that had been reamed prior to insertion to receive the cup. The interface between the bone and cement allowed joint fluid to leak in, and, in many cases, resulted in a high incidence of gradual loosening of the device, osteolysis, and bone loss.

17. Later, a porous metal shell was developed and was offered as a solution to the above-noted problem. However, it was discovered that, after brief clinical experience, these porous metal shells could cause severe destructive osteolysis if the implant was not well designed. This was especially aggravated when screws were used for fixation of the metal shell to the bone structure because a ready fluid path for the joint fluid was provided via the screw holes in the shell which led directly to the resected bone.

18. It was also found that if the polyethylene liner component was poorly fixed within the metal shell, joint fluid could work behind the polyethylene component such that the joint fluid bathed the fixation screws, and such the repeated stresses of walking and weight bearing would force the joint fluid under hydraulic pressure into the bone around the screws. This lead directly to loosening of the device and bone loss.

19. While I have described the above problems in regard to hip replacement systems, the same problems were present in prior total knee arthroplasty.

20. Specifically, in total knee arthroplasty, a polyethylene component that is well fixed to its respective metal component (e.g., a tibial tray or the like), but which allowed joint fluid under the polyethylene component also resulted in a high incidence of severe osteolysis, particularly when such tibial trays did not have a full porous coating that promoted bone growth. In such applications, joint fluid could readily pass under the

polyethylene component, through the screw holes that received bone screws for affixing the tray to the tibia, along the smooth metal surfaces of the tray, and down the stem of the implant into vulnerable cancellous bone and medullary canal below.

21. One attempted solution to this problem in both hip and knee replacement systems was to produce metal components (e.g., acetabular and tibial components) that did not have screw holes. However, in many cases, bone screws are needed to properly affix the components.

22. Another attempted solution to this long-standing problem was to pre-assemble the polyethylene liner to its respective metal component at the factory to achieve rigid fixation of the polyethylene component and the metal component and to prevent the entry of joint fluid through the metal shell and the into the bone. However, these pre-assembled systems were difficult to affix to the bone in surgeries where the patient had experienced bone loss or had soft sub-surface bone structure. It was impossible to see behind the implants to be sure they were seated completely, and the system could not be attached correctly to the bone without screws.

23. This problem of fixing the polyethylene component relative to its respective metal shell or the like has been a long standing problem. In my experience, I have found that most polyethylene components are not rigidly affixed with respect to their respective metal components thus allow micro-motion between the polyethylene and metal components. This micro-motion causes the polyethylene component to wear and to shed microscopic particles which become entrained in the joint fluid and which can lead to damage to the implant. Moreover, all prior systems suffered from the lack of an effective seal.

24. It should be borne in mind that if there is excess joint fluid (which is often the case), the hydraulic pressure can be relatively high. The above-discussed micro-motion of the polyethylene component relative it its metal shell or housing can act as a mechanical hydraulic pump so as to drive the fluid under pressure into the screw holes in the metal component and into the bone around the implant.

25. The devices described in the claims of this reissue application achieve, to my knowledge, for the first time rigid fixation of the polyethylene component within its metal shell or housing and effective sealing between the polyethylene component and its metal tray or shell. At the same time, the polyethylene component may be readily installed by the surgeon during the surgery after the metal component has been affixed to the bone with bone screws and the installation may be done quickly with reasonable insertion forces. Moreover, both the fixation and the seal remain in tact over a long service life in the patient.

26. It cannot be emphasized too strongly that it is vital not only to achieve a rigid fixation of the polyethylene component relative to the metal shell, it is also vital to make a seal that will effectively seal over the life of the system. The particular structure now defined by the remaining claims in this reissue application achieves those requirements.

27. In order to be an effective seal and in order to insure that only a low level of force is needed to insert the liner, the seal must be flexible. A flexible seal will readily deform to allow easy insertion. A flexible seal will sealingly mate with its sealing surface on the metal component. A flexible seal will maintain sealing relation through a million stress cycles, such as the prosthesis device will experience upon the patient

walking over the life of the patient. However, a flexible seal cannot be used to restrain or lock movement of the liner with respect to the shell.

28. I have carefully review the comments by the Examiner in the action mailed May 21, 2002 regarding his rejection of claims 12 and 13 as being obvious over Parchinski (U. S. Patent 4,650,491) in view of Schryver et al. (U. S. Patent 5,314,487).

29. I would first point out that neither Parchinski nor Schryver disclose a prosthesis component that has both a seal and an effective locking system.

30. As the title of Parchinski states, that invention relates to a "Locking System For Prosthesis Components". The prosthesis component described in Parchinski is an acetabular component for a total hip replacement system. It includes a metal shell or cup 12. However, it is noted that the shell 12 of Parchinski is not affixed to the bone structure by means of bone screws. Instead, as described in Col. 2, lines 38 et seq., "The outer surface of shell 12 includes a self-tapping thread 16 which allows prosthesis 10 to be inserted into an acetabulum (not shown) without the use of bone cement."

31. The locking mechanism described in Parchinski is described (at Col. 2, lines 63 et seq. – Col. 3, line 20) as a first annular circumferential rib 38 on the cylindrical portion of the polyethylene insert 14 which is congruent with groove 28 in the interior of the metal shell 12, and a second rib 40 proximate rib 38. As disclosed at Col. 3, line 8 et seq., "when insert 14 is fully assembled within shell 12 as shown in Fig. 5, rib 38 snaps into groove 28 while rib 40 is deformed or flexed and pressed against concavity 18. This latter interference action insures a positive resistance to axial movement or chatter of insert 14 within shell 12 which the combination of rib 38 within groove 28

alone cannot provide. This interference action of rib 40 against concavity 18 also insures positive resistance to rotational chatter of insert 14 within shell 12."

32. Moreover, Parchinski discloses that "the polar region of shell 12 [is] removed to provide a large circular opening 26 for allowing visual assessment of bone apposition during insertion of shell insertion into the acetabulum." (Col. 2, lines 44 – 47). This opening 26 constitutes a direct path for joint fluid to come into contact with the bone structure unless the polyethylene component 14 is effectively sealed with respect to the metal shell 12. Yet, there is no mention whatsoever in Parchinski of the need for a seal between the two components, nor is there any mention that the disclosed locking mechanism performs a sealing function.

33. One of ordinary skill in the art, in 1995 when my patent application was filed would recognize from reading the disclosure of Parchinski, that Parchinski did not even recognize the need for a seal.

34. Moreover, it has been my experience, as one who has invented, designed, developed, tested and used a variety of orthopedic appliances, that the deformable locking rib 40 of Parchinski would not inherently both prevent axial and rotational chatter, as is expressly disclosed in the Parchinski patent, and effectively seal the polyethylene liner 14 with respect to the shell 12.

35. The reason for this is that in order to prevent movement or chatter, the rib 40 must be relatively stiff. However, such a stiff rib design will not have sufficient flexibility to effect a seal. These two functions are counter to one another.

36. Here, I refer to a paper that I co-authored entitled "Effect of Locking Mechanism on Fluid and Particle Flow Through Modular Acetabular Components", as

published in *The Journal of Arthroplasty,* Vol. 13, No. 3, 1998 (pages 254 – 258), a copy of which is attached as Exhibit 1. The research for this paper was conducted by my company, Whiteside Biomechanics, Inc., in part by myself and by the other co-authors of the paper.

37. The purpose of this testing was to determine whether commercially available acetabular components (as listed on page 255) offered a route for joint fluid and debris through the screw holes into the acetabular bone stock. One of the components tested was Whiteside Biomechanics, Inc's. Micro Seal ® acetabular component that is the subject of the above-reissue application. The construction of the Micro Seal ® locking tab and seal of the polyethylene liner are shown in Fig. 1 of the paper. It is seen that this photo (Fig. 1 of the paper) is similar to Fig. 5 of this reissue application.

38. I am familiar with hip joint sockets similar to that described in U. S. Patent 4,596,580 to Weill and assigned to Protek AG of Switzerland. It will be noted that the appliance described in Weill uses a plastic socket member 1 in the general form of a truncated cone. The socket 1 is received in a metal ring member 8 which has a female tapered opening for receiving the tapered conical surface of the socket member 1. As shown in Fig. 1 of the Weill patent, the plastic socket member 1 has four (4) tabs 10 extending radially therefrom. Each of these tabs is received in a respective recess 11. As shown in Fig. 3, each of the tabs 10 is generally of trapezoidal shape having generally horizontal upper and lower surfaces (not numbered) and upwardly and inwardly sloping side surfaces (also not numbered). The corresponding side surfaces of recess 11 also slope upwardly and inwardly of the recess.

39. It will be understood that upon installation of the socket member 1 into the metal ring member 8 of Weill, with the tabs 10 aligned with their respective recesses 11, the bottom surface of the tabs will be wider than the narrow opening of the recess formed by the upwardly and inwardly sloping side surfaces of the recess. Accordingly, in order to insert the tabs into the recess, the plastic tabs must be deformed such that the tabs will forcibly enter the recesses. As can be appreciated from viewing the relative dimensions of the tabs and the recesses in Fig. 3 of Weill, there must be considerable deformation of the tabs to enable insertion into the recesses. Of course, there are four (4) such tabs and recesses used with the device disclosed in the Weill patent and all four of these tabs must be substantially simultaneously inserted into their respective recesses in order to maintain axial alignment of the socket with respect to its ring member. This will require four times the insertion force of a inserting a single tab into a single recess. Thus, the force required to insert the socket into its ring member would be unduly high if the socket were required to be installed in the ring member during surgery after the ring member had been installed on the bone structure. However, because the appliance of Weill does not require bone screws for attachment, it may not be necessary that the socket needs to be installed by the surgeon during surgery, but instead could be factory assembled in which case the high insertion forces would not be a problem.

40. Further, with regard to the Weill patent, I note in Fig. 2 that the bottom end of the plastic socket member 1 extends completely through the tapered opening of the metal ring member 8. I also note that there is no seal, other than the taper surface to tapered surface engagement of the socket within the ring member, that would effectively

prevent the migration of joint fluid or debris to the bone structure at the bottom end of the appliance.

41. With respect to the appliances tested in Exhibit 1, one of the devices tested did have a similar ring and socket member with tapered surfaces similar to what is described in the Weill patent and such appliance did employ the taper locking system as shown in the Weill patent and as described above. This tapered locking system did have an effective seal for preventing the migration of joint fluid and debris. Although a seal could be obtained with this taper-within-a taper mechanism, the polyethylene member was always deformed by seating in the rigid metal taper, and the inner polyethylene surface was distorted. This prevented the femoral head from moving smoothly, and greatly increased the friction in the joint.

42. Further in regard to Exhibit 1, it will be noted that one of the appliances tested was a "Reflection Cup" manufactured by Smith & Nephew of Memphis, TN. I have reviewed U. S. Patent 5,314,487 invented by Mr. Schryver et al. which is assigned to Smith & Nephew. The "Reflection Cup" appliance tested in Exhibit 1 is manufactured by Smith & Nephew and is similar in construction to the appliance described in the Schryver patent. The results of our research clearly show that the locking mechanism of this device did not achieve a seal.

43. In this testing, as described in detail on pages 255 and 256 of the above paper (Exhibit 1), each of the acetabular components was installed in the test setup shown in Figs. 2 and 3 of Exhibit 1. The upper chamber was pressurized to a level of about 300 mm of water and repeated axial and torsional loads were applied using a servo-hydraulic Instron testing machine. The water used to pressurize the upper chamber contained

micro-spheres of polystyrene so that it could be seen whether debris, as well as water which was used to simulate joint fluid, would flow through the interface between the polyethylene component and its shell and thus come into contact with the bone structure. This cyclical loading was applied some 1,000,000 times. The only route for the water between the upper chamber and the lower chamber was through the interface between the polyethylene liner and its shell. This type of restriction of fluid as was achieved by the Smith & Nephew Reflection cup is ineffective since screws are often needed, and since the screws do not seal the screw holes.

44. As a result of this testing, it was determined that the seal around the rim of the Micro Seal ® of the Whiteside polyethylene component (which had the seal and locking structure described in the claims of this reissue application) effectively prevented fluid and particle flow between the metal shell and the polyethylene liner. However, all of the other devices tested passed water and the polystyrene micro-spheres through the liner-to-shell interface and into the collection chamber, except Smith & Nephew's Reflection cup which had a cover in the screw holes.

45. In addition, with my seal design, as described in the claims of this reissue application, only modest forces are required to install the liner within the acetabular shell after the latter has been affixed to the pelvic bone structure with bone screws. These low inserting forces are due in large part to the flexible nature of the seal.

46. The reason that low insertion forces are necessary is that the patients undergoing joint replacement surgery generally have a de-generative bone or joint disease that oftentimes significantly weakens the bone stock supporting the prosthesis components. If high forces are required to install the liner within its metal shell, the bone stock may be very weak and the high insertion forces may cause the bone stock to fail which could put the entire joint structure in jeopardy.

47. I have found that the structure of the seal as shown in Fig. 5 of my patent and as described in claims 10 and 12 of this reissue application makes for low insertion forces. This is due to the fact that the seal is flexible.

48. I have further found that the separate locking tabs and the notches in the shell, as described by the claims of this reissue application, effectively fixes the polyethylene liner rigidly within the metal shell thus preventing micro-motion between the shell and the liner. Moreover, the locking tabs and notches, as described in the claims of my reissue application, result in low insertion forces that will not cause damage to the bone stock and that will not require the surgeon to use undue force.

49. In contrast, upon reviewing the locking tabs and notches disclosed in the newly cited U. S. Patent 4,596,580 to Weill, it would appear that a very high level of insertion force would be required to snap-fit the four (4) tabs or "outwardly extending parts 10" of the socket member 1 into their "correspondingly shaped recesses 11" of the ring member 8.

50. As can be best seen in Fig. 3 of Weill, the notch 11 in ring member 8 has sides 14 which slope downwardly and outwardly of the notch such that the notch is narrower at its top than at its bottom. Likewise, the tab 10 formed on the socket member 1, has sides (not numbered) which slope downwardly and outwardly such that the widest dimension of the tab 10 is at its bottom. Thus, upon insertion of the tabs into the notches, when the tabs are initially aligned with their respective notches, the widest dimension of the tabs will first encounter the narrowest dimension of the notch. This will require significant deformation of the tabs (which as disclosed in Weill at Col.1, line 14) are "frequently made of plastic" such that they will snap fit in the notches. It will be borne in mind that since Weill discloses that the tabs 10 are spaced equally at 90 °, there will be four of the tabs that must be substantially simultaneously inserted into their notches. This will multiply the force required for insert by a factor of 4. It is my view that this may well result in the surgeon having to apply unduly high levels of force to insert the socket member 1 into the ring member 8 which could damage the supporting bone stock on which the ring member is installed.

51. To my knowledge, as of the date of this Declaration (some 7 years after the original filing date of this application), the design described in claims 10 and 12 of

this reissue application is the only such design that achieves a good seal and yet rigidly fixes the polyethylene component within the shell.

Further, deponent sayeth not.

I, the above-named Declarant, hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

9/18/02
Date

Signature of Declarant

Exhibit 1 - "Effect of Locking Mechanism on Fluid and Particle Flow Through Modular Acetabular Components", as published in *The Journal of Arthroplasty*, Vol. 13, No. 3, 1998 (pages 254 – 258).